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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,443	10/02/2001	Donald O. Castell	18596-004	9610

27479 7590 11/29/2004

COCHRAN FREUND & YOUNG LLC
3555 STANFORD ROAD
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FORT COLLINS, CO 80525

EXAMINER

NASSER, ROBERT L

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 11/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/970,443	CASTELL ET AL.	
	Examiner	Art Unit	
	Robert L. Nasser	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7, 8, 10-34, 40, 42-72 and 75-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 42-72 is/are allowed.
- 6) ☒ Claim(s) 1-4, 7, 8, 10-18, 21-30, 32, 34, 40, 75-77 is/are rejected.
- 7) ☒ Claim(s) 19, 20, 31 and 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

The examiner regrets that upon further review of the invention, the following rejection was deemed applicable and the following non-final rejection was made. Applicant is invited to phone the examiner to discuss language to overcome the remaining issues.

Claims 19 and 20 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must be in the alternative. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claims 28, 42, and 76 are objected to because of the following informalities:

Claim 28 is object to in that it is redundant of claim 1.

Claim 42 is objected to in that the word least is spelled lest.

Claim 76 is objected to in that the word for is spelled for5.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10, 21-26, 28, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hickey 5048532. Hickey '532 shows a device including a first probe 11 including a sensor 10 near the distal end and a stabilizing element, the extension of the catheter beyond the balloon, a second probe 21 including sensor 20 and a

stabilizing element, means, one of elements 45 for connecting the two elements together, and an adjustment element, the surgical tape 45, to which the probes are adjustably connected. The examiner notes that the probe of Hickey is for a different purpose than applicants, but notes that applicant has not defined the claim to bring out this distinction. Claim 10 is rejected in that each probe extends from the connection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11, 13-18, 34, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hickey '532 in view of Hickey 5263485. Hickey '485 further teaches the use of a 3rd sensing arrangement, esophageal ekg electrodes and/or the temperature probe in figures 19 and 20, to provide a more detailed picture of a patient's condition. Hence, it would have been obvious to modify Hickey '532 to use such a third arrangement, to enable improved monitoring of the patient. The examiner notes that the spacings of the sensors are "about" that which is claimed. In addition, the probes are adjustable to positioned as claimed. With respect to claim 34, the temperature probe is a 3rd arrangement.

Claims 7, 8, and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hickey '532. The only difference between Hickey and the claimed invention is the signal processing circuit. Hickey requires the signals from balloons 10 and 20 to be

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synchronized in time. Applicant has not stated that the specific circuit solves a stated problem or is for a given purpose. Therefore the exact nature of the processing circuit would have been a mere matter of design choice for one skilled in the art. With respect to claim 7, there is a display in figure 4. The examiner further takes official notice that it is known to allow the user to have a user input in medical devices to allow the physician to set the device as desired.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7, 8, 10-18, 21, 22, 28-30, 32, 34, 75, 76, and 77 are rejected under 35 U.S.C. 102(b) as being anticipated by the Shaker et al article entitled "Esophagopharyngeal Distribution of Refluxed Gastric Acid in Patients with Reflux Laryngitis in view of Dassa et al 5,505,714. Shaker et al discloses two probes, a first one with a single pH sensor adapted to be positioned at a position 5 cm above the LES and a second probe with a second and third pH sensor 10 cm apart (which is "about 7 cm") being configured to straddle the UES. It does not have a clamp to which the probes are adjustably configured. However, Dassa et al further teaches that it is well known to clamp a catheter in place to allow for adjustable locking of the catheter, to ensure proper positioning. Hence, it would have been obvious to modify Shaker et al to use such a clamp, to ensure proper positioning of the probes. The device further has a recorder, i.e. the computer, which receives the data from two data loggers for

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analysis. The computer correlates the two signals with respect to each other and to a user inputted marker signal used to mark some of the claimed events. It has the remaining claim features, noting that the distances in Shaker are "about" the same as the claimed distances. The examiner notes that when the data loggers are connected to the computer, the computer integratively receives the signals, in as much as applicant has not defined integratively receives. Therefore, using the broadest reasonable interpretation, it is the examiner's position that Shaker anticipates the claim feature. With respect to claims 75 and 76, Applicant has not stated that the specific circuit solves a stated problem or is for a given purpose. Therefore the exact nature of the processing circuit would have been a mere matter of design choice for one skilled in the art.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23, 24, and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaker et al in view of Dassa et al, as applied to claims 1-4, 7, 8, 10-22, 28-30, 32, 34, 75, 76, and 77, further in view of Reichstein. Shaker et al does not have the stabilizing element. Reichstein shows an alternate pH probe that has such a stabilizing element. Hence, it would have been obvious to modify Shaker to configure the sensor to have such a stabilizing element, to avoid movement during measurement.

Claims 31 and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 31 and 33 define over the art in that none of the art has a slack portion, as claimed.

Claims 42-72 are allowable. Claims 42-72 define over the art in that none of the art of record teaches taking up the slack, as recited. Applicant's arguments filed December 4, 2003 have been fully considered but they are not persuasive.

Applicant's arguments filed 8/12/004 have been fully considered but they are deemed moot in view of the new grounds of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (571) 272-4731. The examiner can normally be reached on Mon-Fri, variable hours.

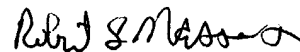
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert L. Nasser
Primary Examiner
Art Unit 3736

RLN
November 22, 2004



ROBERT L. NASSER
PRIMARY EXAMINER